IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL SRL, and ORTHO-MCNEIL, INC.,	)	
Plaintiffs,	)	C.A. No. 07-255-JJF
v.	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	**REDACTED PUBLIC VERSION**
Defendants.	)	

DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR APPLICATION FOR ISSUANCE OF A LETTER OF REQUEST

Of Counsel

Edgar H. Haug
Robert E. Colletti
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Frederick L. Cottrell, III (# 2555)
Cottrell@rlf.com
Steven J. Fineman (#4025)
Fineman@rlf.com
Richards, Layton & Finger P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
Attorneys for Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.

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I. INTRODUCTION

Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., (jointly, "Par") reply to plaintiffs' opposition to Par's motion for issuance of a letter of request to obtain discovery from third-party Grunenthal GmbH ("Grunenthal"). Plaintiffs Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd., and Ortho-McNeil, Inc. (collectively "plaintiffs")[1] seek to prevent Par from obtaining (1) relevant documents, and (2) relevant testimony from a Grunenthal witness in accordance with the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, Oct. 7, 1972, 23 U.S.T. 2555 ("Hague Convention").

Plaintiffs contend that the information sought in Par's letter of request through documents and a deposition of Grunenthal executive board member and former President of Research and Development, Dr. Eric-Paul Paques, is irrelevant to any claim or defense and that the requests are overbroad. That is wrong. The evidence to be obtained from Grunenthal is highly relevant to Par's counterclaims of noninfringement and invalidity.

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[1] Biovail Laboratories International SRL did not join the other plaintiffs in opposing Par's Motion for a Letter of Request.

[2] The terms "controlled-release" and "extended-release" are used interchangeably, herein.

Claim 1 of the '887 patent recites:

> What is claimed is:
> 1 A controlled release oral pharmaceutical preparation suitable for dosing every 24 hours comprising
> a substrate comprising a pharmaceutically effective amount of tramadol or a salt thereof;
> said substrate coated with a controlled release coating;
> said preparation having a dissolution rate in vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0,1 N hydrochloric acid at 37° C. and using UV detection at 270 nm, between 0 and 50% tramadol released after 1 hour; between 0 and 75% tramadol released after 2 hours; between 3 and 95% tramadol released after 4 hours; between 10 and 100% tramadol released after 8 hours; between 20 and 100% tramadol released after 12 hours; between 30 and 100% tramadol released after 16 hours; between 50 and 100% tramadol released after 24 hours; and greater than 80% tramadol released after 36 hours, by weight, said preparation providing a therapeutic effect for about 24 hours after oral administration.

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Par is entitled to discover Grunenthal's development documents related to extended-release tramadol and Grunenthal's

communications with plaintiffs. Contrary to plaintiffs' position, prior art knowledge or use for invalidity purposes is not limited to the United States. *See, e.g.*, 35 U.S.C. § 102(a) ("the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent ...."). Likewise, foreign knowledge and use are relevant for invalidity purposes. *See, e.g.*, 35 U.S.C. § 102(f) ("he did not himself invent the subject matter sought to be patented ...."). Indeed, the '887 patent is invalid if conception of the subject matter was at Grunenthal and the subject matter was subsequently communicated to the plaintiffs in this action.

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Par's letter of request complies with the Hague Convention and should not be modified. Par respectfully requests that this Court sign and date the letter of request so that Par can transmit it to the Central Authority in Dusseldorf.

II. ARGUMENT

A. Proceeding Pursuant To The Hague Convention Is Appropriate In This Case.

Par bears the burden of persuading the Court of the necessity of proceeding pursuant to the Hague Convention. *Tulip Computers Int'l B.V. v. Dell Computer Corp.*, 254 F. Supp. 2d 469, 474 (D. Del. 2003) (quoting *Valois of Am., Inc. v Risdon Corp.*, 183 F.R.D. 344, 346 (D. Conn. 1997) (citations omitted)). "That burden is not great, however, since the 'Convention procedures are available whenever they will facilitate the gathering of evidence by the means authorized in the Convention.'" *Id.* (quoting *Societe Nationale Industrielle Aerospatiale v. United States District Court for the Southern District of Iowa*, 482 U.S. 522, 541 (1987)). Factors relevant to the Court's decision include "considerations of comity, the relative interests of the parties including the interest in avoiding abusive discovery, and the ease and efficiency of alternative formats for discovery." *Id.* (quoting *Madanes v. Madanes*, 199 F.R.D. 135, 141 (S.D.N.Y. 2001) (citations omitted)).

Here, resort to the Hague Convention is appropriate because Grunenthal is not a party to this lawsuit, Grunenthal has not voluntarily subjected itself to discovery, is located in Germany, and is not otherwise subject to the jurisdiction of the Court. Such evidence weighs in favor of proceeding under the Hague Convention. *See id.* at 474 (citing *Orlich v. Helm Brothers, Inc.*, 160 A.D.2d 135, 143 (N.Y. App. Div. 1990) ("When discovery is sought from a non-party in a foreign jurisdiction, application of the Hague [Evidence] Convention, which encompasses principles of international comity, is virtually compulsory.")).

Par has attempted to obtain the requested documents through a subpoena served on Grunenthal USA Inc.[3] But Gruenenthal USA has refused to produce documents on the grounds that the documents are not in its possession, custody, or control. Par disagrees. Grunenthal USA has control over the documents in Germany because (1) Grunenthal USA is an agent of Grunenthal, and (2) Grunenthal USA's sole executive, Sebastian Wirtz, is the Chief Executive Officer of Grunenthal and one of only four members of Grunenthal's executive board. Mr. Wirtz can obtain the requested documents. Nevertheless, because Grunenthal USA refuses to produce the requested documents, Par seeks discovery through the procedures set forth in the Hague Convention.

B. Contrary To Plaintiffs' Assertions, Par's Document Requests Are Not Precluded By German Law.

Plaintiffs argue that Par cannot request documents because "German courts generally do not allow document discovery pursuant to Germany's reservation under Article 23 of the Hague Convention." *See* Plaintiffs' Br. at 9. Plaintiffs' reliance on Article 23 for their argument that pre-trial discovery of documents is generally prohibited in Germany under the Hague Convention is misplaced. In 1987, the United States Supreme Court expressly rejected the argument that Article 23 preempts a request for documents. *Aerospatiale*, 482 U.S. at 536. According to the Court:

> It seems patently obvious that if the Convention were interpreted as preempting interrogatories and document requests, the Convention would really be much more than an agreement on taking evidence abroad. Instead, the Convention would amount to a major regulation of the overall conduct of litigation between nationals of different signatory states, raising a significant possibility of very serious interference with the jurisdiction of United States courts.

[3] The subpoena to Grunenthal USA issued from the Southern District of New York on February 25, 2008. A deposition was not requested.

Id. at 539 (citation omitted) Moreover, the Supreme Court emphasized that Article 27 plainly states that "the Convention does not prevent a contracting state from using more liberal methods of rendering evidence than those authorized by the Convention." *Id.* at 538. Accordingly, "the text of the Evidence Convention, as well as the history of its proposal and ratification by the United States, unambiguously supports the conclusion that it was intended to establish optional procedures that would facilitate the taking of evidence abroad. *See* Amram, The Proposed Convention on the Taking of Evidence Abroad, 55 A.B.A.J. 651, 655 (1969); President's Letter of Transmittal, Sen. Exec. Doc. A, p. III." *Id.*

C. Par's Document Requests And Questions To The Witness Are Proper; They Should Not Be Narrowed Or Stricken.

Plaintiffs contend that Par's discovery requests are unduly broad and overly burdensome. Par disagrees. Regardless, in *Tulip Computers Int'l B.V. v. Dell Computer Corp.*, 254 F. Supp. 2d 469, 475 (D. Del. 2003), the Court held that the breadth of the discovery requests are within the province of the foreign nation, not the U.S. court issuing the letters of request: "[t]he Court is content that such officials will make the appropriate determination under their own law." *See also id.* (citing *Aerospatiale*, 482 U.S. at 542 ("It is well known that the scope of American discovery is often significantly broader than is permitted in other jurisdictions, and we are satisfied that foreign tribunals will recognize that the final decision on the evidence to be used in litigation conducted in American courts must be made by those courts.")). Accordingly, Plaintiffs' attempt to narrow or strike Par's requests for documents relevant to this case based on plaintiffs' interpretation of German law should fail.

All of Par's discovery requests are relevant and tailored to the issues in this case. In order to prove invalidity, Par is entitled to documents showing when and how Grunenthal first developed a controlled-release tramadol formulation. (Topic 4). Moreover, Grunenthal's

reasons and bases for opposing patents and applications around the world corresponding to the '887 patent are relevant to the invalidity of the '887 patent. (Topics 5, 6, 7). Contrary to plaintiffs' position, validity issues are not just limited to prior art. Foreign knowledge and use, which was likely disclosed in Grunenthal's meetings with plaintiffs and in opposition proceedings, are relevant to determine if Grunenthal was first to invent the subject matter disclosed in the '887 patent. Par is entitled to know Grunenthal's relationship with plaintiffs currently and based on past agreements for purposes of determining bias. (Topics 8, 9). Par is also entitled to learn the history of tramadol and discover why and how Grunenthal developed its controlled-release product. (Topics 3, 4).

Additionally, the '366 patent opposition proceeding (Topics 5, 6) is relevant because Grunenthal opposed a patent that corresponds to the '887 patent and after settling with plaintiffs, that patent was revoked. Grunenthal's bases for opposing the '366 patent and reasons for settling the case before the '366 patent was revoked is relevant. If certain information is privileged, the witness can invoke privilege. Also on this issue, Par disagrees with plaintiffs that "it is not contested" that the '366 patent was revoked on a "technicality" of European Law. *See* Plaintiffs' Br. at 1-2. Instead, this "technicality" appears to be very similar to a 35 U.S.C. § 112 invalidity determination for having a claim that is broader than the specification can support. For at least these reasons, the document requests and topics are properly tailored and should not be limited in any way.

D. Public Knowledge And Use Are Not Limited to Activities In The United States For 35 U.S.C. § 102 Purposes.

According to Purdue, "By statute, public knowledge and use by others are prior art under 35 U.S.C. § 102 only as to activities in the United States; foreign knowledge and use are not prior art." *See* Plaintiffs' Br. at 3. Plaintiffs are wrong. At least 35 U.S.C. § 102(a) and

35 U.S.C. § 102(f) concern foreign knowledge and use by others for purposes of invalidating the '887 patent. 35 U.S.C. § 102 states:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> * * *
>
> (f) he did not himself invent the subject matter sought to be patented, or

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Regardless, Par is entitled to discovery on Grunenthal's development and correspondence with plaintiffs regarding controlled-release tramadol in the early to mid 1990s to determine whether the '887 patent is invalid. The scope of the document requests to Grunenthal are properly tailored and the questions set forth to Dr. Paques are appropriate. Therefore, the discovery requests should not be modified in any way.

III. CONCLUSION

For the foregoing reasons and for the reasons set forth in Par's Motion for Issuance of a Letter of Request, Par respectfully requests that the Court sign and date the letter of request so that Par can transmit it to the Central Authority in Dusseldorf.

Frederick L. Cottrell, III (# 2555)
Cottrell@rlf.com
Steven J. Fineman (#4025)
Fineman@rlf.com
Richards, Layton & Finger P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
Attorneys for Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.

Of Counsel

Edgar H. Haug
Robert E. Colletti
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Dated: March 28, 2008

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DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on April 8, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

Jack B. Blumenfeld, Esquire
Rodger D. Smith II, Esquire
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

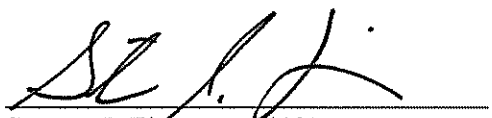
Richard D. Kirk, Esquire
The Bayard Firm
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899-5130

Mary W. Bourke, Esquire
Conolly Bove Lodge & Hutz LLP
The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899

I hereby certify that on April 8, 2008, I have sent by Electronic Mail, the foregoing document to the following non-registered participants:

Robert J. Goldman, Esquire
Ropes & Gray LLP
525 University Avenue
Suite 300
Palo Alto, California 94310

Richard A. Inz
Sona De
Ropes & Gray LLP
1211 Avenue of the Americas
New York, New York 10036



Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, Delaware 19899
(302) 651-7700
fineman@rlf.com

EXHIBITS A & B ARE

REDACTED IN THEIR ENTIRETY